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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,619	03/02/2004	Henry B. Lowman	P1123R1DIC1	4016

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EXAMINER	
SZPERKA, MICHAEL EDWARD	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,619	LOWMAN ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response and amendments received November 22, 2005 are acknowledged.

Claims 48 and 55 have been amended.

Claims 48-65 are pending in the instant application and are under examination in this office action.

Specification

2. Applicant is thanked for amending the first line of the specification to update the status of applications to which priority has been claimed.

The objection to the specification concerning the discussion of experiment VI and other typographical errors has been withdrawn in light of applicant's amendment to correct obvious errors noted in the office action mailed June 29, 2005.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any additional errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 48-65 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of prophylactically administering a humanized anti-IgE antibody that reduces the onset of IgE-mediated disorders, does not reasonably provide enablement for a method of administering an antibody at anytime that prevents the onset of IgE-mediated disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant's arguments and claim amendments received November 22, 2005 address some, but not all, of the issues raised in the rejection of record set forth in the office action mailed June 29, 2005. Specifically, applicant has amended the claims to recite humanized antibodies, thus rendering that part of the rejection moot. Applicant also acknowledges that anaphylactic shock, a condition encompassed by the breadth of applicant's claims, can be fatal in minutes and must be treated with epinephrine. Applicant then argues that administration of anti-IgE antibodies is therapeutically beneficial to treat anaphylaxis when administered subsequent to antigen exposure, and indicates that Chang et al. (of record) teach that the administration of anti-IgE antibodies will be therapeutically significant once more clinical trials are concluded, and that Leung et al. (indicated in applicant's reply as being listed in a supplemental IDS, but no such form accompanied applicant's response and as such it has been made of record in the 892 that accompanies this office action) demonstrate the therapeutic efficacy of anti-IgE therapy. Applicant's arguments and evidence do not show that anti-IgE antibodies

remove the soluble mediators already released by degranulation that contribute to the signs and symptoms of IgE-mediated disorders including the precipitous drop in blood pressure in anaphylactic shock. The art of Leung et al. cited by applicant involves prophylactically administering an anti-IgE antibody to patients *prior* to peanut allergen challenge. As such, there does not appear to be any evidence, either in the art or in applicant's specification, that demonstrate that administration of an anti-IgE antibody *subsequent* to allergen exposure can control the soluble mediators which would have already been released, such mediators causing the signs and symptoms of IgE-mediated disorders such as anaphylactic shock. Note that the recitation "preventing the onset" does not necessarily mean that the antibody is administered prophylactically, especially since as noted above applicant argues that administering anti-IgE antibodies, without any apparent reference to when such administration must be performed, is therapeutic in treating anaphylaxis.

Applicant's amendments to the claims also raise a new issue due to the word "prevent". While the specification does indicate that anti-IgE antibodies are to be used for prevention, the specification does not appear to indicate any range of therapeutic efficacy that defines prevention. As evidenced by the teachings of Leung et al. entered by applicant to demonstrate the therapeutic efficacy of administering anti-IgE antibodies, not all patients receiving prophylactic administration of anti-IgE antibodies fail to demonstrate IgE-mediated symptoms when challenged with peanut allergens (see entire document, particularly Figure 2). Webster's New World Dictionary defines "prevent" as to keep from happening; make impossible by prior action (Third College

Edition, 1988, see page 1067). As such, a skilled artisan would interpret "prevent" to mean that therapeutic administration of anti-IgE antibodies is efficacious in each and every patient, but the teachings of Leung et al. clearly demonstrate that this is incorrect. As such, a skilled artisan would be unable to practice the full breadth of applicant's claimed methods without conduction additional research.

Amending the claims to recite "A method of reducing the onset ... comprising prophylactically administering ..." would be more concordant with the teachings of the art including Leung et al. since it would not require 100% efficacy, and such language appears to be supported in lines 19-25 of page 3 and original claims 24-27. It is possible that other language supported in the specification can also be found that would be of similar effect.

5. The art of Wadee et al. (J. Allergy Clin Immunol 1987, 80:695-8, see entire document) and Reimers et al. (Clin Exp Allergy 2000, 30:276-82, see entire document) have been cited by the examiner as being of interest to the claimed subject matter.

6. No claims are allowable.

7. Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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February 2, 2006

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